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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/530,752	04/08/2005	Shuh Narumiya	Q87373	7330
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23373	7590	11/30/2006
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SUITE 800
WASHINGTON, DC 20037

EXAMINER

GRAFFEO, MICHEL

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 11/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/530,752

Applicant(s)

NARUMIYA, SHUH

Examiner

Michel Graffeo

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9,11-13,15 and 17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9,11-13,15 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Action

Claims 9, 11-13, 15 and 17 are examined.

Applicant has amended claims 9, 11-13 and 15 canceled claims 1-8, 10, 14 and 16 and added claim 17 and provided arguments for the patentability of claims 9, 11-13, 15 and 17 in the response filed 17 July 2006.

Applicant's arguments, see response, filed 17 July 2006, have been fully considered and are persuasive to the extent that the rejections under 35 U.S.C. 101, 35 U.S.C. 102 and 35 USC §112, have been withdrawn. Any rejection not specifically stated in this Office Action has been withdrawn.

Priority

Receipt is acknowledged of Applicant's claim to priority of JP 2002 297900 and of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Election/Restrictions

Applicant thanks the Examiner for rejoinder of Group I, but it is noted that claims 1-8 are cancelled.

Art Unit: 1614

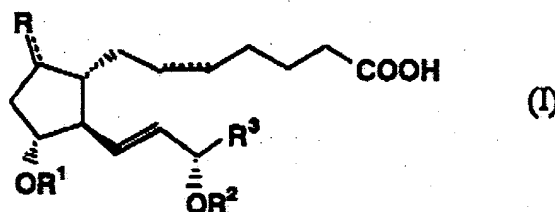
Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9, 11-13, 15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 1008588 to Ono Pharmaceutical Co., Inc. in view of Sheller et al. The prostaglandin E agonist, misoprostol, inhibits airway IL-5 production in atopic asthmatics. Prostaglandins & other Lipid Mediators 70 (2002) 185-193.

The '588 reference discloses the a compound and pharmaceutical comprising a compound having the following general structure:



The '588 reference does not teach that EP3 agonists are effective in treating allergies such as asthma.

Sheller et al. teach that misoprostol is effective in treating atopic asthma (see Title) via signaling through the EP3 receptor (see Discussion page 190).

One of ordinary skill in the art would have been motivated to combine the above references and as combined teach the claimed invention. One of ordinary skill in the art would have been motivated to combine the '588 reference and Sheller et al. because

Art Unit: 1614

both are directed to agonizing EP3 and the inhibition of prostaglandin E2. Moreover, the selection of a known material based on its suitability for its intended use can support a prima facie obviousness determination and herein the teachings of Sheller et al. that agonizing PGE2 receptors such as EP3, results in a reduction of IL-5 and evidently eosinophils, mast cells and/or T lymphocyte production (all inflammatory cells), in light of the teaching in the '588 reference that EP3 is a recognized receptor for PGE2 makes a case of prima facie obviousness. Finally, combining agents which are known to be useful for allergies individually into a single composition useful for the very same purpose is prima facie obvious. See *In re Kerkhoven* 205 USPQ 1069. Since it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose, the idea of combining the claimed active and anti-asthma drugs flows logically from their having been individually taught in the prior art. Thus, the combined references teach and make prima facie obvious how to use the claimed invention at the time that it was made.

Response to Arguments

Applicant's arguments filed 17 July 2006 have been fully considered but they are not persuasive. Applicant's argue that the Sheller et al. reference does not teach that an EP3 agonist can be used to treat an allergic disease. To the contrary, Sheller et al. teach that misoprostol can be used to treat atopic asthma (as recited in claim 12). That Sheller et al. may not have unraveled the mechanism of action of the active agent does

Art Unit: 1614

not detract from its use as art since it teaches the limitations of the claims. For the same reason, one of ordinary skill in the art would have expected success upon the combination of the two references.

Conclusion

No claim is allowed.

Applicant's amendment, newly added claim 17, necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michel Graffeo whose telephone number is 571-272-8505. The examiner can normally be reached on 9am to 5:30pm Monday to Friday.

Art Unit: 1614

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

20 November 2006
MG


ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER